Original Article

Comparison of clinical performance of Baska mask and Ambu AuraGain in patients undergoing surgery: A single-blinded, randomised comparative trial

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ABSTRACT

Background and Aims: The Baska mask (BM) and the Ambu AuraGain (AAG) have shown promising results in recent trials but have not been compared. Therefore, we aimed to compare the clinical performance of the BM and the AAG for airway management of adult patients. **Methods:** In this randomised comparative study, patients aged 18–60 years and with an expected surgical duration of less than 2 h were enroled. Patients were randomly allocated to AAG (Group A, $n = 37$) and BM (Group B, $n = 37$) for airway management. After induction of anaesthesia, an allocated supraglottic airway device (SAD) was inserted. Oropharyngeal leak pressure (OLP), time taken to insert SAD, number of insertion attempts, leak fraction (LF), first-attempt success rate, overall success rate, ease of insertion, fiberoptic view of the glottis, and complications were compared. The data were analysed using Student's *t*-test, Mann–Whitney *U* test, and Fisher's exact tests. **Results:** Baseline and demographic characteristics were comparable. OLP (31.32 ± 2.59 versus 27.54 ± 1.32 cmH_2O) was higher ($P < 0.001$), and LF (6.19% ± 1.20% versus 7.24% ± 1.72%) was lower ($P = 0.003$) in the BM group. First-attempt and overall success rate, time taken to insert, number of insertion attempts, ease of insertion, and fibreoptic view of glottis through the SADs were statistically similar between groups. However, the incidence of sore throat ($P = 0.007$) and cough ($P = 0.028$) was higher with AAG. **Conclusion:** Clinical performance of BM was better than AAG as the former had higher OLP, lower LF and complications.

Keywords: Airway management, Ambu AuraGain, Baska mask, laryngeal masks, oropharyngeal leak pressure, supraglottic airway devices

INTRODUCTION

Supraglottic airway devices (SADs) are important tools for airway management in the perioperative period. The Baska mask (BM) and the Ambu AuraGain (AAG) are two recently introduced SADs.[1,2] Both devices have unique design elements and have shown promising clinical performance in recent trials.[3-6] These airway equipment have high oropharyngeal leak pressure (OLP) and a high first-attempt success rate with low leak fraction (LF) and shorter device insertion time. The BM and the AAG have been compared with other SADs in a previous trial.[3-6] However, no study compared the BM and the AAG. Hence, this trial compared the clinical performance of the BM and the AAG in adult patients undergoing elective surgery. The study aimed to determine which of the two SADs had higher OLP when used for airway management in patients undergoing elective surgical procedures. The null hypothesis was that the BM and the AAG have no difference in OLP when used for airway management in patients undergoing elective surgical procedures.

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METHODS

This single-blinded, randomised, comparative study was conducted after receiving approval from the ethics committee (vide approval No. 1916/ethics/2021, dated 30 December 2021) and after registering the trial with the Clinical Trials Registry - India (vide registration number CTRI/2022/05/042544, www.ctri.nic.in). Informed and written consent for research and educational purposes was taken from all the patients in the study after explaining the study protocol to them. The study procedure followed the guidelines stated in the Declaration of Helsinki, 2013. It was carried out from May 2022 to December 2022. The inclusion criteria were patients with American Society of Anesthesiologists (ASA) physical status I and II, aged 18–60 years, who were scheduled for elective surgery under general anaesthesia with an expected duration of surgery less than 2 h. The exclusion criteria were patients with an anticipated difficult airway, obesity, cardiac or pulmonary diseases, risk of aspiration, pregnancy, and undergoing thoracic, cardiovascular, and head and neck surgeries. Pre-anaesthetic check-up of the participants was done one day before the surgery. Recruited patients were randomised using computer-generated random numbers and allocated to one of the following groups using a sequentially numbered opaque, sealed envelope technique:

Group A (n = 37): airway was managed with AAG (Ambu A/S, Ballerup, Denmark)

Group B (n = 37): airway was managed with a BM (Proact Medical Systems, Frenchs Forest NSW, Australia)

Random numbers for randomisation were generated using Microsoft Excel (version 2302) software (Microsoft Corporation, WA, USA). Sequentially numbered, opaque, sealed envelopes for simple randomisation were prepared by author RR; SR enroled participants, and RP assigned participants to interventions. After the patients arrived at the operating theatre, monitors (pulse oximeter, non-invasive blood pressure, and electrocardiogram) were attached. The patients were blinded to the intervention allocated to them. The envelope containing the patient's group allocation was opened in a separate adjacent room, and the allocated SAD was prepared. Devices of sizes 3, 4, and 5 were used for airway management in patients weighing 30–50 kg, 50–70 kg, and 70–100 kg, respectively, for both the SADs. The SAD was brought into the operating theatre after induction of anaesthesia. Induction of anaesthesia was done using intravenous fentanyl 2 μg/kg, titrated doses of propofol 1.5–2.5 mg/kg, and vecuronium 0.1 mg/kg. The designated SAD was inserted according to the manufacturer's recommendation after adequate neuromuscular blockade by an anaesthesiologist with at least three years of experience in using SAD.[7,8] The AAG's cuff pressure was kept under 60 cmH_2O. Correct positioning was confirmed via capnography and chest auscultation. One more insertion attempt was allowed if the first attempt failed. A sevoflurane–oxygen–nitrous oxide mixture and intermittent doses of intravenous vecuronium were used to maintain anaesthesia.

Time taken for device insertion was measured from the anaesthesiologist first picking up the SAD and successful device placement. For measurement of OLP, the anaesthesia ventilator was set to manual or spontaneous mode, adjustable pressure-limiting valve was set to 40 cmH_2O and flow to 3 L/min. A stethoscope was placed on the lateral aspect of the thyroid cartilage, and the pressure at which an audible leak was heard using the stethoscope was noted as the OLP.[9] LF (measured in percentage) was recorded by dividing the difference between inspired and expired tidal volume with the inspired tidal volume. A fibreoptic view (FOV) of the larynx was obtained by inserting a 5.5-mm flexible bronchoscope through the airway tube of the SAD. The FOV was graded on the following scale: (1) whole glottis visible; (2) glottis visible partially; (3) glottis not visible, only epiglottis visible; and (4) no identifiable laryngeal structures seen.[10] Ease of SAD insertion was graded as per the following classification: (1) SAD placed without any resistance in the first attempt; (2) successful placement of SAD in the first attempt but with resistance; (3) SAD placed in the second attempt; and (4) SAD could not be placed in two attempts.[10] The first-attempt success rate, overall success rate, and the number of attempts required to insert the SAD were also recorded. The above variables were measured before the start of the surgery. After the end of the surgery, anaesthetics were discontinued, and muscle relaxant was antagonised. The SAD was removed after the patient regained consciousness and after adequate muscle relaxant reversal. Perioperative complications within 24 h of SAD insertion were recorded.

OLP was the primary outcome variable. The secondary outcome variables were first-attempt success rate and overall success rate of SAD insertion, number of attempts required for SAD placement, time taken for SAD insertion, ease of SAD placement, LF, and complications.

The sample size was calculated using OpenEpi version 3.01 (www.OpenEpi.com) for detecting a difference of 5 cmH_2O in OLP between the two groups. Based on previous studies, OLP had a standard deviation of 6.8 cmH_2O for the BM and 7.5 cmH_2O for the AAG.[11,12] For a type I error of 0.05 and a power of 0.8, 33 participants were required in each group. To account for data loss and patient exclusions, 37 participants were recruited in each group. Continuous data were compared using Student's *t*-test. Ordinal data were compared using the Mann–Whitney *U* test. Fisher's exact test was used for the analysis of dichotomous data. Data were compared using Statistical Package for the Social Sciences (SPSS) statistics version 25 (International Business Machines, New York, USA) for Windows. Data were presented as mean ± Standard deviation (SD), median (interquartile range) or number (percentage). A two-sided *P* value less than 0.05 was considered statistically significant for all the tests.

RESULTS

The flow of the patients through the study is shown in Figure 1. Baseline and demographic data were statistically similar between the two groups [Table 1]. Parameters representing the clinical performance of the SADs are summarised in Table 2. OLP was statistically higher and LF lower in Group B. Time taken for SAD insertion, ease of insertion, and FOV were statistically similar between groups. The overall success rate of device insertion was 100% in both the groups ($P = 1.00$). SADs were inserted in the first attempt in 35 participants in Group A and 34 in Group B ($P = 1.00$). The median (interquartile range) for ease of SAD insertion was 1 (1–2) for Group A and 1 (1–1) for Group B ($P = 0.460$). The median (interquartile range) for FOV was 1 (1–1) for both groups ($P = 0.19$). No patient had grade 4 FOV or ease of insertion in the trial. The incidence of sore throat and cough were statistically higher with the AAG [Table 3].

Table 1: Baseline and demographic characteristics of the patients in Group A (Ambu AuraGain) and Group B (Baska mask)

	Group A (*n*=37)	Group B (*n*=37)	*P*
Age (years)	40.46 (8.55)	38.89 (9.37)	0.455
Height (cm)	162.16 (5.87)	164.24 (7.14)	0.175
Weight (kg)	63.38 (6.31)	64.92 (7.72)	0.350
BMI (kg/m^2)	24.11 (2.24)	24.06 (2.32)	0.915
Gender ratio (M:F)	19:18	15:22	0.484
ASA (I/II)	14/23	10/27	0.457
Type of surgery:			
Abdominal	13	11	0.929
Breast surgery	11	13	
Orthopaedic	8	7	
Gynaecological	5	6	

Data represented as mean (standard deviation) or numbers. BMI=body mass index, M=male, F=female, ASA=American Society of Anesthesiologists

DISCUSSION

We observed that the BM had significantly higher OLP and low LF than the AAG. First-attempt success rate, overall success rate, time taken for insertion of SAD, FOV, and ease of SAD insertion were similar. The frequency of cough and sore throat was statistically higher with the AAG.

Both the BM and the AAG are cuffed peri-laryngeal sealers, with the airway seal achieved by apposition of the devices' cuff with the larynx and peri-laryngeal tissues.[13] In our study, the BM had higher OLP and lower LF than the AAG. This implies that the BM had a better laryngeal seal than the AAG during positive pressure ventilation. OLP is considered a marker of correct placement of SAD in the airway.[14,15] Although both devices have not been compared previously, both have shown high OLP in previous studies.[3-6,11,16] The intracuff pressure of the BM's membranous cuff increases with increasing airway pressure, potentially improving the airway seal and OLP.[11] This was probably responsible for the higher OLP of the BM in our study. A similar mechanism may be responsible for the lower LF observed with the BM. LF was much lower than the generally acceptable LF, less than 15%. Low LF implies an adequate seal between the larynx and the SAD mask. A low LF facilitates positive pressure ventilation, especially at higher airway pressures. A low LF also reduces the wastage of anaesthetic gases, air pollution, and the risk of gastric insufflation.[17] In previous studies, both devices have shown low LF with positive pressure ventilation.[3-5,11,16]

Previous studies have also found the insertion of both devices to be easy.[3,11,18] Previous studies have also shown a high success rate with both devices.[3,16,18,19] FOV was similar for both groups, with the glottis being visible in more than 90% of cases. Other

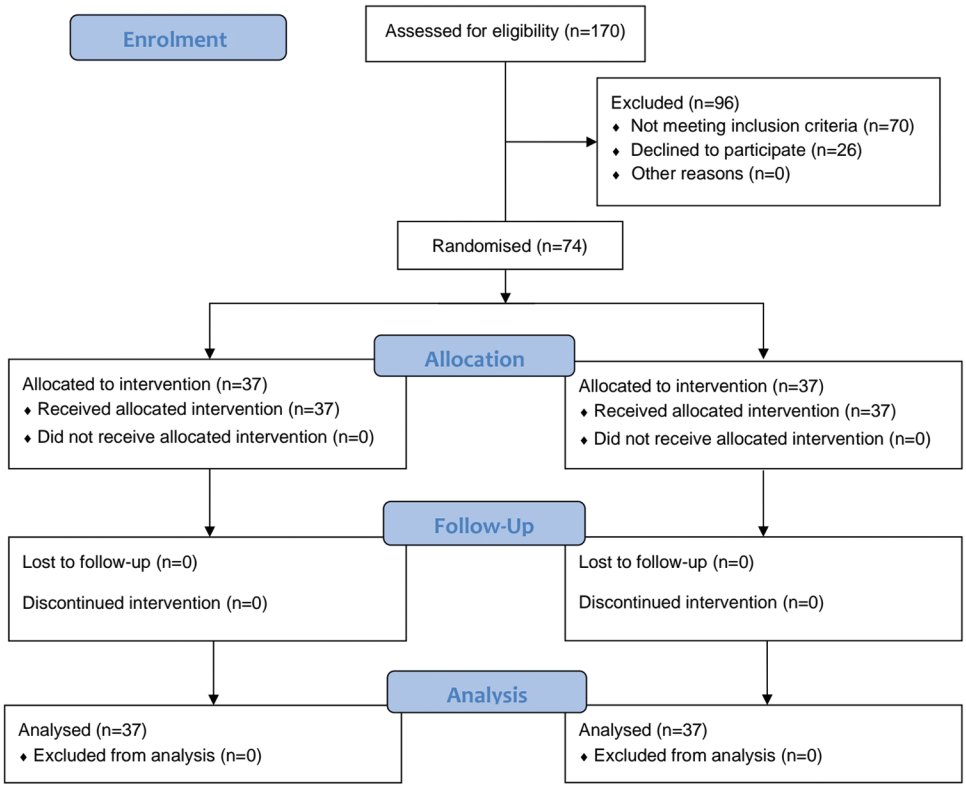

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) diagram showing the flow of patients through the trial

Table 2: Clinical performance of the airway devices in Group A (Ambu AuraGain) and Group B (Baska mask)

Parameter	Group A (n=37)	Group B (n=37)	*P*	Effect size
Insertion time (s)	13.41 (2.25) (12.68–14.13)	13.27 (1.10) (12.92–13.62)	0.744	0.079
OLP (cmH_2O)	27.54 (1.32) (27.11–27.97)	31.32 (2.59) (30.49–32.16)	<0.001	−1.839
LF (%)	7.24 (1.72) (6.69–7.79)	6.19 (1.20) (5.80–6.58)	0.003	0.708
Number of attempts (1/2)	35/2	34/3	1.000	
Ease of insertion (1/2/3)	21/14/2	25/9/3	0.461	
FOV (1/2/3)	28/7/2	33/3/1	0.189	

Data represented as mean (standard deviation) (95% CI) or numbers. CI=confidence intervals, OLP=oropharyngeal leak pressure, LF=leak fraction, FOV=fibreoptic view

Table 3: Incidence of side effects in Group A (Ambu AuraGain) and Group B (Baska mask)

Complications	Group A (*n*=37)	Group B (*n*=37)	*P*
Sore throat	9	1	0.007
Cough	8	1	0.028
Gastric distension	2	2	1.000
Blood on device	1	2	1.000

Data represented as numbers

studies also found visibility for both devices greater than 90%.[3,5,16,18] The visibility of the glottis using a bronchoscope inserted through the airway tube of SAD has two implications: First, it represents the correct position and alignment of the SADs with the larynx.[15] Second, the fibreoptic bronchoscope-guided endotracheal intubation through the SADs is expected to be easier for devices with a better view of the glottis.[18]

In our study, the cough and sore throat frequency among the participants was statistically higher with the AAG than with the BM. The cuff of the BM inflates only during inspiration. The mask's design also ensures that the pressure exerted on peri-laryngeal tissues is limited to the peak inspiratory pressure. The risk of intraoperative rise of cuff pressure due to the diffusion of nitrous oxide into the cuff of the mask is also absent with this design. In the AAG, the pressure by the cuff on the larynx and peri-laryngeal tissues is exerted throughout the respiratory cycle and is typically higher than the airway pressure.[8,20] Diffusion of nitrous oxide into the cuff of the AAG may also raise intra-cuff pressures during surgery. These factors may be responsible for the greater incidence of sore throat and cough associated with the AAG.

Limitations include the single-blinded and single-centre design of the study. The study included both laparoscopic and non-laparoscopic surgeries. However, all the measurements, except the complications, were obtained before surgery.

CONCLUSION

The BM is superior to AAG as the former has higher OLP and lower LF with fewer complications.

Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared after approval as per the authors' Institution policy

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Nil.

Conflicts of interest

There are no conflicts of interest.

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